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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/851,664	DE LEYS ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31 and 37-44* is/are pending in the application.

4a) Of the above claim(s) *38-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,37 and 41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5-2-2005 has been entered.

Claim Rejections Withdrawn

The new matter rejection of claims 31, 37 and 41 are rejected under 35 U.S.C. 112, first paragraph, is withdrawn in light of the amendment thereto.

The rejection of claim 41 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the phrase "stringent hybridization conditions" is withdrawn in light of the amendment thereto.

The rejection of claim 41 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "specifically hybridizes" is withdrawn in light of the amendment thereto.

The rejection of claims 31 and 41 under 35 U.S.C. 102(b) as being anticipated by Montagnier et al. (WO 86/02383 – IDS- 5/9/2001) is withdrawn in light of the amendment thereto. The cited reference does not disclose the specific hybridization conditions recited in the instant claims.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 31 and 41-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the previous Office action in the rejection of claims 31and 41.

Applicant argues:

1. As amended, claim 41 specifically defines "stringent conditions".
2. The recited conditions are exemplary.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, as stated in the rejection, the specification discloses SEQ ID NO:1 that corresponds to a portion of the HIV-3 cDNA (iso 70-11 clone). SEQ ID NO:1 meets the written description provision of 35 USC 112, first paragraph (which is why claim 37 was not included in the rejection). However, the aforementioned claims are directed to encompass the vast genus of probes that

specifically hybridize to genomic RNA (or any species of RNA) of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. This vast genus fails to meet the written description provision of 35 USC 112, first paragraph. Recitation of specific hybridization conditions does not overcome this failure.

As outlined previously, the specification discloses SEQ ID NO:1 that corresponds to a portion of the HIV-3 cDNA (iso 70-11 clone). SEQ ID NO:1 meets the written description provision of 35 USC 112, first paragraph. However, the aforementioned claims are directed to encompass probes that specifically hybridize to genomic RNA (and any other RNA species) of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed."* (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found

unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

> Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2datl966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Moreover, while SEQ ID NO:1 is disclosed, the specification is silent as to whether said sequence will meet the functional limitations of the rejected claims. Therefore, there are no disclosed probe sequences that meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Enablement Rejection

Claims 31, 37 and 41-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the previous Office action in the rejection of claims 31, 37 and 41. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues:

1. The term "stringent conditions" is defined in the specification (page 17, lines 16-24).
2. The instant claims no longer recite the limitation "specifically hybridizes" and the hybridization parameters are set forth in the instant claims.
3. In view of the biological deposit, one of skill in the art would have no trouble making and using probes that hybridize with the genomic RNA of the retrovirus deposited at the European collection of Animal cell Cultures (ECACC) under No. V88060301 without undue experimentation.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, the term "stringent conditions" is explicitly (or implicitly) defined in the specification. The specification merely recites one possibility. The use of open language suggests that more (undefined) conditions can also be considered "stringent". (see above).

With regard to Point 2, the recitation of specific hybridization conditions is insufficient to provide enablement.

With regard to Point 3, the probes of claimed invention are not limited to those derived **from** the deposited material. They encompass all probes that hybridize **to** the genomic RNA of the deposited material.

Claims 31,and 41-43 encompass polynucleotides (DNA probes) comprising non-disclosed nucleic acid sequences that **hybridize** to the genomic RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301 under stringent conditions. Claims 37 and 44 are drawn to DNA probes comprising SEQ ID NO:1 or the complement of SEQ ID NO:1. As disclosed above, the specification does not teach how to make any polynucleotides that specifically hybridizes to the genomic RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. Clearly, since the specification has not taught how to make/use said polynucleotides, the specification has not enabled the instant claims that require DNA probes that specifically hybridize to the genomic RNA of the HIV-3 retrovirus deposited at the European Collection of Animal Cell Cultures (ECACC) under No. V88060301. Said probes include those comprising SEQ ID NO:1 or the complement of thereof. When given the broadest reasonable interpretation, the claims are clearly intended to encompass a variety of species including full-length cDNAs, genes and protein coding regions. Moreover, the use of the term "comprising" (claims 37 and 44) and "contains" (claim 31 and 43) reads on intact genomic material comprising enhancers, promoters, introns, and splice sites, etc. No open reading frames are identified in any sequence such that one of skill in the art would be able to determine where such features could be within the sequence. Clearly, it would be expected that a substantial number of the hybridizing or complementary polynucleotides encompassed by the claims would

not share either structural or functional properties with polynucleotides that encode SEQ ID NO:1 or its complement. The specification fails to provide an enabling disclosure for how one would make such polynucleotides. Moreover, the specification is silent as how one would detect a non-genomic RNA species using a probe that hybridizes to genomic RNA. The specification provides insufficient guidance with regard to these issues and provides no working examples that would provide guidance to one skilled in the art on how to make/use the broadly claimed genus. For the above reasons, undue experimentation would be required to practice the claimed invention. Hence, the rejection is deemed proper and is maintained.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 42 to recite "stringent conditions comprise conditions at least as stringent as...". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent. Therefore this limitation is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is rendered vague and indefinite by the use of the phrase stringent conditions comprise conditions at least as stringent as...". It is unclear what criteria are used to determine relative "stringency". Nor is it clear how said criteria would be measured. Since the specification is silent with regard to these matters it is impossible to determine the metes and bounds of the claimed invention.

35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims are rejected 42-43 under 35 U.S.C. 102(b) as being anticipated by Montagnier et al. (WO 86/02383 – IDS- 5/9/2001).

Montagnier et al. disclose methods for the use of DNA hybridization probes for the detection of LAV (HIV) in tissues and fluids (see page 38-39). Moreover, said methods utilize stringent conditions even though Montagnier et al. do not explicitly disclose them. This is

evidenced by the fact that Montagnier et al. disclose that that methods for screening for evolutionary related retroviruses are performed using non stringent conditions (as opposed to stringent conditions used in the other disclosed methods)[see page 39, lines 10-12]. Consequently, it is deemed, in the absence of evidence to the contrary, that one of the probes encompassed by the Montagnier et al. disclosure will be effective in the detection of HIV-3 or its RNA since the hybridization conditions have not been defined (see above).

Conclusion

No claim is allowed.

SEQ ID NO:1 is free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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ROBERT A. ZEMAN
PATENT EXAMINER

Robert A. Zeman
July 12, 2005